REMARKS

I. Disposition of the Claims

Claims 1-2, 4-9, and 11-22 are pending and elected claims 16-22 should be examined. Claim 16 was amended as shown. Support for the amendment is, e.g., in the as-filed specification paragraph 81.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 16-22 in condition for allowance. Applicants submit that the proposed amendment of claim 16 does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, because all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully note that the final action by the Examiner presented some new arguments as to the application of the art against the elected invention. It is respectfully submitted that the entering of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance or at least would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In summary, it is submitted that the amendment would be properly enterable under Rule 116(b)(2) (An amendment presenting rejected claims in better form for consideration on appeal may be admitted). Thus, the Examiner is respectfully requested to enter the present amendment.

II. Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 16-22 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Office action, p. 2. The Examiner's reasons boil down to two basic comments, which are taken in reverse order from their appearance in the Office action.

According to the rejection, the second reason is that "[t]he claims as written do not specify the polypeptides needed for detection of antibodies." Office action, p. 2. The current version of the claims now recites a polypeptide. For example, claim 16 reads:

> 16. (Currently Amended) A method for detecting and quantifying at least one antibody directed against a circovirus of type PCVB by an Enzyme-Linked Immunosorbent Assay (ELISA) method**, wherein the at least one antibody is capable of binding to a polypeptide encoded by a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ ID NO: 23, SEQ ID NO: 25, or SEQ ID NO: 27**.

Claims 17-22 depend from claim 16. Thus, it is believed that the Examiner's second reason is not an obstacle for allowing the present version of the claims.

According to the rejection, the first reason is that "the specification only asserts that [the polypeptide encoded by ORF'2] is capable of recognizing the antibodies produced by PWD circovirus type B [cite omitted]. Therefore, Applicants' assertion is not commensurate with the teachings of the scope of the disclosure." Office action, p. 2. It is submitted that the first reason is not an obstacle to enablement either.

As noted of record, the specification makes clear that ELISA may be performed, as described at page 34, lines 1-14. As disclosed in Example 6, the specification provides direct guidance for detecting and quantifying porcine circovirus antibodies using, for example, ELISA.

It was also emphasized that Applicants have characterized and expressed SEQ ID NOS: 23, 25, and 27, i.e., ORF'1-'3, and it is believed that no other reference of record describes an analogous characterization or expression. Claim 16 now recites *a polypeptide encoded by a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ ID NO: 23, SEQ ID NO: 25, or SEQ ID NO: 27.*

It is believed that the Examiner would agree that embodiments using the polypeptide encoded by *a nucleic acid having a nucleotide sequence with at least 90% sequence identity to ... SEQ ID NO: 25* would have been enabled, because the Examiner stated that "the specification

only asserts that [the polypeptide encoded by ORF'2] is capable of recognizing the antibodies produced by PWD circovirus type B."

As for embodiments using the *polypeptide encoded by a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ ID NO: 23 ...*, it is submitted that example 5 allowed the present inventors to conclude that "proteins encoded by [SEQ ID NOs: 23 and 25] ... are immunogenic proteins ...." As a result, it is believed that the Examiner would agree that embodiments using the polypeptide encoded by *a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ ID NO: 23 [or] SEQ ID NO: 25* would have been enabled.

As for embodiments using the *polypeptide encoded by a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ ID NO: 23 ... or SEQ ID NO: 27*, it is submitted that one of ordinary skill in the art could have been capable of designing an ELISA detection method around a denatured linear protein and an antibody capable of binding to the denatured protein.

As an aside, it is worth noting now that the present invention differs from that described of Wang '639 (*vide infra*), because Wang '639's claim 42 recites detecting antibodies from a biological sample. Thus, while Wang '639's claim 42 would be limited to detecting antibodies raised by structural proteins, the present version of claim 16 is not so limited.

In summary, it is believed that neither the Examiner's first nor the Examiner's second reason is an obstacle for allowing the present version of the claims. And because, for the reasons explained of record, the as-filed specification provides sufficient direction and guidance for detecting antibodies directed against a porcine circovirus of Type B, the rejected claims are supported by an enabling disclosure. Accordingly, the rejection should be withdrawn.

III. Rejections under 35 U.S.C. § 112, second paragraph (indefinite description)

Claims 16-22 were rejected under 35 U.S.C. § 112, second paragraph, for alleged lack of an essential element, i.e., the antigen. Office action, p. 3. The present version of claim 16 now recites *a polypeptide encoded by a nucleic acid having a nucleotide sequence with at least 90%*

sequence identity to SEQ ID NO: 23, SEQ ID NO: 25, or SEQ ID NO: 27. Claims 17-22 depend from claim 16. As a result, the present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

IV. Rejection under 35 U.S.C. § 102(e)

Claims 16-22 were rejected as anticipated by the publication no. 2002-0106639 A1 ("Wang '639"). Wang '639, titled *Postweaning multisystemic wasting syndrome virus from pigs*, names four Inventors (Wang, Li; Babiuk, Lorne A.; Potter, Andrew A.; and Willson, Philip), and is assigned on its face to the University of Saskatchewan. It resulted from application no. 09/935,428, filed August 20, 2001.

The '428 application claims priority to application no. 09/209,961, filed December 10, 1998 (Wang '639's parent application), which application claimed the benefit of provisional application nos. 60/069,233, filed December 11, 1997 (Wang's provisional I), and 60/069,750, filed December 16, 1997 (Wang's provisional II).

It is submitted that the present claims are entitled to an effective filing date not later than that of the parent international application, i.e., December 4, 1998, a date before the filing date of Wang '639's parent application, which was filed December 10, 1998. Thus, the focus of the comments that follow is why, as to the cited ELISA subject matter, Wang '639 is not prior art as of either of Wang's provisional's filing date.

If an application publication claims the benefit of priority of a provisional application under § 119(e), then the critical reference date is the filing date of the provisional if and only if the provisional properly supports the subject matter relied upon for the rejection in a manner that complies with § 112, first paragraph. MPEP § 2136.03 III.

In the present case, the rejection relied upon claims 42 and 30 of the publication, which read as follows:

> 42. A method of *detecting porcine circovirus Type II (PCVII) antibodies* in a biological sample comprising: (a) providing a biological sample; (b) reacting said biological sample with an

> immunogenic PCVII polypeptide according to claim 30, under conditions which allow PCVII antibodies, when present in the biological sample, to bind to said PCVII polypeptide to form an antibody/antigen complex; and (c) detecting the presence or absence of said complex, thereby detecting the presence or absence of PCVII antibodies in said sample. **{See paragraphs 13-17 and 129, 133-34, 172, 185, and 187-42.}**
>
> 30. An immunogenic porcine circovirus Type II (PCVII) polypeptide having at least about 85% identity to a polypeptide selected from the group consisting of a polypeptide derived from (a) open reading frame (ORF) 1 (SEQ ID NO:3), (b) ORF 2 (SEQ ID NO:9), (c) ORF 3 (SEQ ID NO:7), (d) ORF 4 (SEQ ID NO:20), (e) ORF 5 (SEQ ID NO:21), (f) ORF 6 (SEQ ID NO:5), and (g) immunogenic fragments of (a)-(f) comprising at least about 5 amino acids. **{See paragraph 10 and figures 3A-D.}**

The information in the bolded brackets seems to correspond to supporting passages in the disclosure of Wang '639.

As will be explained below, the critical date of the cited passages of Wang '639 cannot be antedated to the filing date of either of Wang's provisionals, because neither provisional supports, in the manner required by § 112, first paragraph, the subject matter relied upon for the present rejection. Thus, the critical date of Wang '639 is after the effective filing date of the present claims, and Wang '639 is not prior art as to the present claims.

A. ***Wang '639 is not prior art as of Wang's provisional I's filing date.***

Wang's provisional I is three pages long plus figures and other supporting papers. It discloses the "cloning and sequencing" of clone 412, the only noticeable statement of utility of which concerns "diagnosis and vaccine development."

> The cloning and sequencing of the novel circovirus provides information about the causative agent of PMWS. The sequencing information, the clone and its gene products are useful in diagnosis and vaccine development.

Wang's provisional I, p. 2. As Wang's provisional I fails to describe *detecting any antibody*, Wang's provisional I does not properly support, in a manner that complies with § 112, first paragraph, the cited subject matter relied upon in the rejection. Thus, as to the cited subject matter, the critical date of Wang '639 cannot be antedated to the filing date of Wang's provisional I.

B. ***Wang '639 is not prior art as of Wang's provisional II's filing date.***

Wang's provisional II contains some, but not all, of the descriptions relevant to the material cited in support of the present rejection. After comparing the disclosure of Wang's provisional II with that of Wang '639, however, it is submitted that the Examiner will agree that Wang's provisional II does not properly support, in a manner that complies with § 112, first paragraph, the cited subject matter relied upon in the rejection. Thus, as to the cited subject matter, the critical date of Wang '639 cannot be antedated to the filing date of Wang's provisional II.

To facilitate the comparison, the following table is useful for referencing. The table's first two columns refer to passages related to ELISA from Wang '639 and Wang's provisional II. The table's third column states the effect of the comparable disclosures or lack thereof.

Passages of Wang '639 related to ELISA	Comparable passages in Wang's Provisional II	Effect
[0013] The invention also relates to the methods of preparing polypeptide compositions, such as vaccines and immunodiagnostic compositions, and immunoglobulins, and to immunoassays and kits for assays containing the primers, probes, polypeptides, and/or immunoglobulins. In one embodiment, then, the invention pertains to a method of detecting PCVII antibodies in a biological sample comprising: [0014] (a) providing a biological sample; [0015] (b) reacting the biological sample with an immunogenic PCVII polypeptide as described above, under conditions which allow PCVII antibodies, when present in the biological sample, to bind to the PCVII polypeptide to form an antibody/antigen complex; and [0016] (c) detecting the presence or absence of the complex, [0017] thereby detecting the presence or absence of PCVII antibodies in the sample.	None.	This description cannot be used against the claims of the present application.
[0129] As explained above, the proteins of the present invention may also be used as diagnostics to detect the presence of reactive antibodies of PCVII in a biological sample in order to determine the presence of PCVII infection. For example, the presence of antibodies reactive with the proteins can be detected using standard electrophoretic and immunodiagnostic techniques, including immunoassays such as competition, direct reaction, or sandwich type assays. Such assays include, but are not limited to, Western blots; agglutination tests; enzyme-labeled and mediated immunoassays, such as ELISAs; biotin/avidin type assays; radioimmunoassays; immunoelectrophoresis; immunoprecipitation, etc. The reactions generally include revealing labels such as fluorescent, chemiluminescent, radioactive, enzymatic labels or dye molecules, or other methods for detecting the formation of a complex between the antigen and the antibody or antibodies reacted therewith.	As explained above, the proteins of the present invention may also be used as diagnostics to detect the presence of reactive antibodies of PCV in a biological sample in order to determine the presence of PCV infection. For example, the presence of antibodies reactive with the proteins can be detected using standard electrophoretic and immunodiagnostic techniques, including immunoassays such as competition, direct reaction, or sandwich type assays. Such assays include, but are not limited to, Western blots; agglutination	The description states a wish or a plan to use ELISA or a possibility to use ELISA.

Passages of Wang '639 related to ELISA	Comparable passages in Wang's Provisional II	Effect
	tests; enzyme-labeled and mediated immunoassays, such as ELISAs; biotin/avidin type assays; radioimmunoassay; immunoelectrophoresis; immunoprecipitation, etc. The reactions generally include revealing labels such as fluorescent, chemiluminescent, radioactive, enzymatic labels or dye molecules, or other methods for detecting the formation of a complex between the antigen and the antibody or antibodies reacted therewith. p. 25, ll. 18-25.	

Passages of Wang '639 related to ELISA	Comparable passages in Wang's Provisional II	Effect
[0133] More particularly, an ELISA method can be used, wherein the wells of a microtiter plate are coated with a desired protein. A biological sample containing or suspected of containing anti-protein immunoglobulin molecules is then added to the coated wells. After a period of incubation sufficient to allow antibody binding to the immobilized antigen, the plate(s) can be washed to remove unbound moieties and a detectably labeled secondary binding molecule added. The secondary binding molecule is allowed to react with any captured sample antibodies, the plate washed and the presence of the secondary binding molecule detected using methods well known in the art. [0134] Thus, in one particular embodiment, the presence of bound anti-antigen ligands from a biological sample can be readily detected using a secondary binder comprising an antibody directed against the antibody ligands. A number of anti-porcine immunoglobulin (Ig) molecules are known in the art which can be readily conjugated to a detectable enzyme label, such as horseradish peroxidase, alkaline phosphatase or urease, using methods known to those of skill in the art. An appropriate enzyme substrate is then used to generate a detectable signal. In other related embodiments, competitive-type ELISA techniques can be practiced using methods known to those skilled in the art.	More particularly, an ELISA method can be used, wherein the wells of a microtiter plate are coated with a desired protein. A biological sample containing or suspected of containing anti-protein immunoglobulin molecules is then added to the coated wells. After a period of incubation sufficient to allow antibody binding to the immobilized antigen, the plate(s) can be washed to remove unbound moieties and a detectably labeled secondary binding molecule added. The secondary binding molecule is allowed to react with any captured sample antibodies, the plate washed and the presence of the secondary binding molecule detected using methods well known in the art. Thus, in one particular embodiment, the presence of bound anti-antigen ligands from a biological sample can be readily detected	The description provides general descriptions of embodiments of the ELISA technique, which are not specific to any antigen or antibody. Thus, paragraphs 133-34 do not add much more than what paragraph 129 added.

Passages of Wang '639 related to ELISA	Comparable passages in Wang's Provisional II	Effect
	using a secondary binder comprising an antibody directed against the antibody ligands. A number of anti-porcine immunoglobulin (Ig) molecules are known in the art which can be readily conjugated to a detectable enzyme label, such as horseradish peroxidase, alkaline phosphatase or urease, using methods known to those of skill in the art. An appropriate enzyme substrate is then used to generate a detectable signal. In other related embodiments, competitive-type ELISA techniques can be practiced using methods known to those skilled in the art. p. 27, l. 11-p. 28, l. 2.	
[0171] ELISA. [0172] Purified PCV was diluted in sodium carbonate buffer (0.05 M) pH 9.6 to a concentration of 0.5 μg per 100 μl and used to coat Immulon II plates (Dynatech Laboratories, Inc.). The plates were washed six times with TTBS (20 mM Tris-HCl, 500 mM NaCl, 0.05% of Tween 20, pH 7.5) before serially diluted primary rabbit or pig antibody was	None.	This description cannot be used against the claims of the present application.

Passages of Wang '639 related to ELISA	Comparable passages in Wang's Provisional II	Effect
added. After six washes with TTBS, alkaline phosphatase-conjugated secondary antibodies (1/5000 dilution), either anti-rabbit or anti-pig (Kirkegaard & Perry), were added. Plates were developed with 100 μl/well of p-Nitrophenyl Phosphate (PNPP, 3 g/L) in 1 M diethanolamine, 0.5 $MgCl_2$, pH 9.8 and the plates were read on an ELISA reader (BioRad) at 405/490 nm.		
[0185] To determine the presence of an infectious causative agent(s) for PMWS, various tissues from pig #412, an experimentally challenged piglet sacrificed 21 days post-infection, were used for viral isolation. After continued passage of lymph node samples from pig #412 in Dulac cells, virus accumulation or adaptation was observed. A unique pattern of cytopathic effect initially developed, followed by increasing virus titer, as determined by ELISA using the standard Berlin anti-PCV antibody, as described above.	None.	This description cannot be used against the claims of the present application.
[0187] Because it appeared that porcine circoviruses possessed some heterogeneity, ELISAs were performed using sera of piglets, collected from a herd with a PMWS outbreak, against the PCV and isolate PCVII 412 virus. Most of the asymptomatically PCVII-infected and convalescent piglets developed specific antibodies against PCVII, not PCVI.	None.	This description cannot be used against the claims of the present application.

The comparable passages in Wang's provisional II do not support, in a manner required by § 112, first paragraph, the cited subject matter of the rejection, i.e., *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample*, because Wang's provisional II never described the viral protein(s) present in *a biological sample*, let alone an antibody raised by that protein. As a result, the critical date of Wang '639 cannot be antedated to the filing date of Wang's provisional II.

The following statements are couched in the familiar language of the *Wands* factors, specially adapted to the task of determining whether or not Wang's provisional II supports, in a manner required by § 112, first paragraph, *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *Nature of the cited disclosure of Wang '639.* Claim 42 of Wang '639 is noted in full above and will be summarized here:

> *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* comprising: (a) providing a biological sample; (b) reacting said biological sample with an *immunogenic PCVII polypeptide* according to claim 30, under conditions which allow PCVII antibodies, when present in the biological sample, to bind to said PCVII polypeptide to form an antibody/antigen complex; and (c) detecting the presence or absence of said complex, thereby detecting the presence or absence of PCVII antibodies in said sample

(Emphasis added). Because the *detecting* is performed on a *biological sample*, it is submitted that the *antibodies* would be formed against the structural proteins as noted by the Examiner on page 2 of the Office action. As a pool of proteins to select from, the cited disclosure is claim 30, which reads:

> 30. An immunogenic porcine circovirus Type II (PCVII) polypeptide having at least about 85% identity to a polypeptide selected from the group consisting of a polypeptide derived from (a) open reading frame (ORF) 1 (SEQ ID NO:3), (b) ORF 2 (SEQ ID NO:9), (c) ORF 3 (SEQ ID NO:7), (d) ORF 4 (SEQ ID NO:20), (e) ORF 5 (SEQ ID NO:21), (f) ORF 6 (SEQ ID NO:5), and (g) immunogenic fragments of (a)-(f) comprising at least about 5 amino acids.

(Emphasis added). Clearly, which of these proteins, if any, is capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639 is not apparent from the nature of the invention *per se*. In any case, the pool of proteins to select from is very large.

- *The state of the prior art at the time Wang's provisional II was filed..* Wang '639 never described isolating RNAs encoding proteins. As such, it is assumed that Wang '639 used computer programs for ORF prediction.

Simply put, such computer programs are not always correct and usually require experimental data to definitively prove the function of the predicted genes or ORFs. In other words, many computer-predicted genes or ORFs would have no function at all. Indeed, until one actually isolates the RNAs encoding the viral proteins, makes the cDNA from those RNAs, and then expresses the cDNA to make the viral protein, one cannot conclusively identify the correct sequences representing the ORFs encoding the viral proteins. And once the viral proteins are identified, in the context of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* according to Wang '639, one would have to further experiment to determine which proteins would bind to the *antibodies* in the *biological sample*. Clearly, in the present context, one of ordinary skill in the art could not detect *porcine circovirus Type II (PCVII) antibodies* without first identifying the correct viral protein.

Along these lines, given the very large pool of viral proteins to select from, it is unclear if Wang '639 is in possession of the right protein(s) capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639. Thus, the state of the art in the context of Wang '639 tends to show that, to antedate the critical date, Wang's provisional II should contain an actual working example due to the low degree of predictability of finding a useful protein capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *The level of one of ordinary skill at the time Wang's provisional II was filed was low enough to require experimentation and further discovery.* Even if one of ordinary skill in the art could use ELISA at the time when Wang's provisional II was filed, one of ordinary skill in the art, guided by the teachings of Wang's provisional II, would not innately be able to determine which protein from the large pool of proteins is capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *The level of predictability in the art was low.* Due to the very large pool of viral proteins to select from, and the state of the art in the context of Wang '639, there is a low degree

of predictability of finding a useful protein capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *The lack of the existence of working examples.* No examples of Wang '639 can be used against the claims of the present application, as no Examples in Wang '639 are disclosed in Wang's provisional II. Clearly, the lack of working examples in Wang's provisional II tends to show that Wang's provisional II does not properly support, in a manner that complies with § 112, first paragraph, *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *The amount of direction provided by Wang '639 was low.* According to the comparison, Wang's provisional II states a wish or a plan to use ELISA or states the possibility to use ELISA. Along these lines, Wang's provisional II provides general descriptions of embodiments of the technique, which are not specific to any antigen or antibody. Moreover, due to the very large pool of viral proteins to select from, it would be hard to find a useful protein capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639. Clearly, the low amount of direction in Wang's provisional II tends to show that Wang's provisional II does not properly support, in a manner that complies with § 112, first paragraph, *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

- *The quantity of experimentation needed to make the invention based on the content of Wang's provisional II's disclosure at the time Wang's provisional II was filed was undue.* Due to the very large pool of viral proteins to select from, it is unclear if Wang '639 is in possession of any protein(s) capable of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639. Wang's provisional II never provided any guidance, e.g., a working example, raising an antibody, etc. Furthermore, Wang '639 never described isolating the RNAs encoding the viral proteins, making the cDNA from those RNAs, and then expressing the cDNA to make the viral protein to conclusively identify the correct sequences representing the ORFs encoding the

viral proteins. And once the viral proteins are identified, in the context of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* according to Wang '639, one would have to further experiment to determine which proteins would bind to the *antibodies* in the *biological sample*. Clearly, in the present context, one of ordinary skill in the art could not detect *porcine circovirus Type II (PCVII) antibodies* without first identifying the correct viral protein through undue experimentation.

- Based on weighing the sum of all these factors, "undue experimentation" would have been needed for one of ordinary skill in the art to make use of *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639.

As a result, Wang's provisional II does not properly support, in a manner that complies with § 112, first paragraph, the cited subject matter relied upon in the rejection. Thus, as to *detecting porcine circovirus Type II (PCVII) antibodies in a biological sample* in the context of Wang '639, the critical date cannot be antedated the filing date of Wang's provisional II.

Because the critical date of Wang '639 cannot be antedated the filing date of Wang's provisional II, the cited disclosures of Wang '639 cannot be before the effective filing date of the present claims, and Wang '639 cannot be prior art as to the present claims. Thus, the rejection should be withdrawn.

V. Conclusion

It is believed that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

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